K081233

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JUL 28 2008

Section 7 – 510(k) Summary

I. Applicant Information

A. Applicant: Spectros Corporation
4379 Alpine Road, Suite 108
Portola Valley, CA 94028

B. Official Contact: Bill Curnan
Director of Quality/Regulatory
Spectros Corporation
4379 Alpine Road, Suite 108
Portola Valley, CA 94028

C. Date of Summary: 4/21/08

II. Device Information

A. Proprietary Name : T-Stat™ 303 Microvascular Tissue Oximeter

B. Common Name: Tissue Oximeter

C. Classification Name: Oximeter, Tissue (870.2700)

D. Product Code: MUD

E. Regulatory Class: II

F. Panel: Cardiovascular

III. Predicate Device

The device in this 510(k) represents a modification to the T-Stat 303™ Microvascular Tissue Oximeter approved in 510(k) K040684 which is the predicate device.

IV. General Description

The Spectros T-Stat™ 303 Tissue Oximeter is a broadband,

multiwavelength, Visible Light Spectroscopy (VLS) monitoring system for measuring the saturation of hemoglobin with oxygen in the microvascular tissue spaces (StO2%).

The complete system consists of a disposable sensor probe connected to a software-driven electronic monitor. Data collection, analysis, and display functions are provided by the monitor. Illumination of the tissue is provided by a visible light source in the sensor probe placed near, on, or into the target tissue to be studied. Reflected light is captured and returned to the monitor via a detachable connection at the monitor end of the patient probe. StO2% is estimated using differential optical diffuse reflectance spectroscopy and fitting for background scattering over a range of reflected visible wavelengths.

V. Indications

The Spectros T-Stat™ 303 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces (StO2%) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states.

The prospective clinical value of measurements made with the T-Stat™ Oximeter has not been demonstrated in disease states. The T-Stat™ Oximeter should not be used as the sole basis for diagnosis or therapy.

VI. Comparison to Predicate

The system in this 510(k) represents a modification to the T-Stat303™ Oximeter System described in the predicate 510(k), K040684. These modifications consist of

1. Monitor housing changed from all metal to a molded housing with a metal front and back plate.
2. Addition of a shorter (.5M) Endoscopic Probe to the probe set for use in applications where the existing 2.3M length is excessive.
3. Addition of a smaller oral probe to the probe set to provide a better fit in smaller patients
4. Updated software which has eliminated some annoyance bugs and clarified user interface.

VII. Test Summary

A. Monitor tests on the new housing consist of re-verification of compliance with IEC60601-1-2 and a shipping test per ISTA-1a.
B. The normal manufacturing final test and inspection was determined to be the only validation required.
C. Sterilization process was revalidated with the new smaller oral probe.
D. Software updates were revalidated using an in house validation procedure.

VIII. Conclusions

Based upon the above test results the modified T-Stat 303™ Oximeter System represents an improvement over the predicate with better software performance, equivalent safety performance, and improved probe assortment that allows for better patient fit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2008

Spectros Corporation
c/o Mr. Bill Curnan
Director of Quality/Regulatory
4370 Alpine Road, Suite 108
Portola Valley, CA 94028

Re: K081233
Trade/Device Name: T-Stat 303 Microvascular Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: MUD
Dated: June 25, 2008
Received: June 27, 2008

Dear Mr. Curnan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081233

Device Name: Spectros T-Stat™ 303 Microvascular Tissue Oximeter

Indications For Use: The Spectros T-Stat™ 303 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces (StO_2%) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states.

The prospective clinical value of measurements made with the T-Stat™ Oximeter has not been demonstrated in disease states. The T-Stat™ Oximeter should not be used as the sole basis for diagnosis or therapy.

Prescription Use 1 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081233